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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,876	12/01/2003	Renu Wadhwa	14875-066003	3083

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EXAMINER	
BELYAVSKYI, MICHAIL A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/725,876	WADHWA ET AL.	
	Examiner	Art Unit	
	Michail A. Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-53* is/are pending in the application.

4a) Of the above claim(s) *52 and 53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-50* is/are rejected.

7)☒ Claim(s) *34-41 and 51* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/684,573

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/01/03; 02/04/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 06/29/05 is acknowledged.

Claims 34-53 are pending.

Applicant's election without traverse of Group I, claims 34-51 in the reply filed on 06/29/05 is acknowledged.

2. Claims 52-53 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 34-51 reads on an isolated antibody that specifically binds to a polypeptide comprising of the amino acid sequence of SEQ ID NO:1 are under consideration in the instant application.

3. The specification on page 1, line 4 should be amended to reflect the status of the parent 09/684,579 application

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed.*

5. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/684,579 , filed on 10/06/2000.

6. Applicant's IDS, filed 12/01/03 and 02/04/05 are acknowledged. A references cited in IDS filed on 12/01/03 have been filed in parent Application 09/684,579 filed on 10/06/2000.

7. The specification is objected to under 37 CFR 1.821(d) for failing to disclose SEQ ID NOS, for the amino acid sequence disclosed on page 18, line 2.

8. The Specification is objected to because of the following informalities: on page 4, line 5-10 the Specification disclosed " The nucleotide sequence of striamin cDNA derived from mouse DNA is shown in SEQ ID NO:1". It is noted that SEQ ID NO:1 is an amino acid sequence of a striamin protein, encoded by cDNA of SEQ ID NO:2.

Appropriate correction is required.

9. Claims 34-41 and 51 are objected to because of the following informalities: It is improper to recite " An isolated antibody that specifically binds to a polypeptide the amino acid sequence of which is set forth in SEQ ID NO:1" or " An isolated antibody that specifically binds to a polypeptide the amino acid sequence of which consists of residues 76 through 149 or 1 through 75 of SEQ ID NO:1". It is suggested that said phrase be amended to recite "An isolated antibody that specifically binds to a polypeptide consisting of SEQ ID NO:1" and " An isolated antibody that specifically binds to a polypeptide consisting of residues 76 through 149 or 1 through 75 of SEQ ID NO:1".

10. Claim 42 is objected to because of the following informalities: It is improper to recite " An isolated antibody or portion thereof, produced by immunizing...". It is suggested that said phase be amended to recite " An isolated antibody or antigen-binding portion thereof, wherein the antibody is produced by immunizing... ".

11. Claims 43-50 are objected to because of the following informalities: It is improper to recite " An isolated antibody or portion thereof, ...". It is suggested that said phase be amended to recite " An isolated antibody or antigen-binding portion thereof, ... ".

Appropriate correction is required.

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 42-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: (i) an isolated antibody and antigen-binding portion thereof wherein said antibody is produced by immunizing an animal with a polypeptide **consisting of** at least 30 or at least 50 contiguous amino acid residues of SEQ ID NO:1; or (ii) an isolated antibody and antigen-binding portion thereof that specifically binds to a polypeptide **consisting of** the amino acid sequence of residues 1 through 75 or 76 through 149 SEQ ID NO:1 or comprising the amino acid sequence of SEQ ID NO:1 does not reasonably provide enablement for: an isolated antibody and portion thereof produced by immunizing an animal with a polypeptide **comprising** at least 30 or at least 50 contiguous amino acid residues of SEQ ID NO:1, as recited in claims 42 and 43; or (ii) an isolated antibody and antigen-binding portion thereof that

specifically binds to a polypeptide **comprising** the amino acid sequence of residues 1 through 75 or 76 through 149 SEQ ID NO:1, as recited in claims 45 and 46. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification does not enable one of skill in the art to practice the invention as claimed without undue experimentation.
The claims as written encompass the genus of antibodies that can specifically bind polypeptides wherein such polypeptides have numerous differences in amino acid sequences.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, limited working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

Applicant disclosed a novel striamin protein of SEQ ID NO:1, encoded by a nucleic acid of SEQ ID NO:2 that can inhibits the differentiation of myoblast into myotubes (see entire Specification, page 4, lines 1-10 in particular). Applicant also disclosed antibody that specifically binds said polypeptide and can be used for purification, detection of said protein or for antibody therapy (see pages 5, 16 and 34 in particular). Applicant has not taught how to make and/or use : (i) any isolated antibody and portion thereof produced by immunizing an animal with a polypeptide comprising at least 30 or at least 50 contiguous amino acid residues of SEQ ID NO:1, as recited in claims 42 and 43; or (ii) an isolated antibody and antigen-binding portion thereof that specifically binds to a polypeptide comprising the amino acid sequence of residues 1 through 75 or 76 through 149 SEQ ID NO:1, as recited in claims 45 and 46. . The structural and functional characteristics of said polypeptides are not defined in the claim. Applicant has not provided sufficient biochemical information (e.g. structural characteristics, amino acid composition , physicochemical properties, etc) that distinctly identifies *any* polypeptide comprising at least 30 or at least 50 contiguous amino acid residues of SEQ ID NO:1 or any polypeptide comprising the amino acid sequence of residues 1 through 75 or 76 through 149 SEQ ID NO:1 other than a polypeptide consisting of SEQ ID NO:1 that are capable to inhibits the differentiation of myoblast into myotubes. While any "*any* polypeptide comprising at least 30 or at least 50 contiguous amino acid residues of SEQ ID NO:1 or any polypeptide comprising the amino acid sequence of residues 1 through 75 or 76 through 149 SEQ ID NO:1" may have some notion of the activity of the " striamin protein of SEQ ID NO:1", claiming biochemical molecules by such properties fails to provide sufficient guidance and direction as to how the skilled artisan can make and use such antigens, to prepare antibody that can be used for purification and detection striamin protein of SEQ ID NO:1 or for antibody therapy commensurate in scope with the claimed invention.

"Comprising" is considered open-ended claim language and includes amino acid residues outside of the specified peptide. It means that a peptide may include additional unrecited amino acid on either or both of the N or C-terminus of a given sequence . Therefore, a peptide "comprising" comprising at least 30 or at least 50 contiguous amino acid residues of SEQ ID NO:1 or any polypeptide comprising the amino acid sequence of residues 1 through 75 or 76 through 149 SEQ ID NO:1 other than a polypeptide consisting of SEQ ID NO:1 includes an unlimited number of amino acid sequences "comprising" an unlimited number of polypeptides. The disclosure of striamin protein of SEQ ID NO:1 cannot support the entire genus of peptides comprising at least 30 or at least 50 contiguous amino acid residues of SEQ ID NO:1 or any polypeptide comprising the amino acid sequence of residues 1 through 75 or 76 through 149 SEQ ID NO:1 as part of their sequence that can that can inhibits the differentiation of myoblast into myotubes)

Colman *et al.,* in Research in Immunology (145(1):33-36, 1994) teach single amino acid changes in an antigen can effectively abolish antibody antigen binding. Abaza *et al.,* in Journal of Protein Chemistry (11(5):433-444, 1992) teach that single amino acid substitutions outside the antigenic site on a protein effect antibody binding. Further, Lederman *et al* in Molecular Immunology (28:1171-1181, 1991) disclose that a single amino acid substitution in a common allele ablates binding of a monoclonal antibody (see entire document). Moreover, Whisstock et al (Quarterly Review of Biophysics, 2003, 36, pp307-340) teaches that prediction of protein function from sequence and structure is difficult problem, because homologous proteins often have different function. A fundamental problem is that function is in many cases an ill-defined concept (see Abstract in particular). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see in particular "Abstract" and Box 2). Finally, even single amino acid differences can result in drastically altered functions between two proteins. For example, Metzler et al. (Nature Structural Biol. 1997; 4:527-531) show that any of a variety of single amino acid changes can alter or abolish the ability of CTLA4 to interact with its ligands CD80 and CD86 (e.g., summarized in Table 2). Thus it is unpredictable if any functional activity will be shared by two polypeptides having less than 100% identity over the full length of their sequences.

Thus, Applicant has not provided sufficient guidance to enable one skill in the art to use claimed an isolated antibody and portion thereof produced by immunizing an animal with a polypeptide **comprising** at least 30 or at least 50 contiguous amino acid residues of SEQ ID NO:1, as recited in claims 42 and 43; or (ii) an isolated antibody and antigen-binding portion thereof that specifically binds to a polypeptide **comprising** the amino acid sequence of residues 1 through 75 or 76 through 149 SEQ ID NO:1, as recited in claims 45 and 46 in manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement. *In re Fisher*, 166 USPQ 18(CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification, the limited working examples, and the limited amount of direction provided given the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

13. Claims 42-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of: an isolated antibody and antigen-binding portion thereof wherein said antibody is produced by immunizing an animal with a polypeptide **consisting of** at least 30 or at least 50 contiguous amino acid residues of SEQ ID NO:1; or (ii) an isolated antibody and antigen-binding portion thereof that specifically binds to a polypeptide **consisting of** the amino acid sequence of residues 1 through 75 or 76 through 149 SEQ ID NO:1 or comprising the amino acid sequence of SEQ ID NO:1.

Applicant is not in possession of: an isolated antibody and portion thereof produced by immunizing an animal with a polypeptide comprising at least 30 or at least 50 contiguous amino acid residues of SEQ ID NO:1, as recited in claims 42 and 43; or (ii) an isolated antibody and antigen-binding portion thereof that specifically binds to a polypeptide comprising the amino acid sequence of residues 1 through 75 or 76 through 149 SEQ ID NO:1, as recited in claims 45 and 46

The claimed invention is drawn to a genus of antibody and portion thereof produced by immunizing an animal with a polypeptide comprising at least 30 or at least 50 contiguous amino acid residues of SEQ ID NO:1, or (ii) an isolated antibody and antigen-binding portion thereof that specifically binds to a polypeptide comprising the amino acid sequence of residues 1 through 75 or 76 through 149 SEQ ID NO:1, however, structural identifying characteristics of the genus are not disclosed. There is no evidence that there is any *per se* structure/function relationship between the disclosed an isolated antibody and antigen-binding portion thereof wherein said antibody is produced by immunizing an animal with a polypeptide consisting of at least 30 or at least 50 contiguous amino acid residues of SEQ ID NO:1; or (ii) an isolated antibody and antigen-binding portion thereof that specifically binds to a polypeptide consisting of the amino acid sequence of residues 1 through 75 or 76 through 149 SEQ ID NO:1 or comprising the amino acid sequence of SEQ ID NO:1 that can be used for purification and detection striamin protein of SEQ ID NO:1 or for antibody therapy and other that may be found using the claimed method. The specification does not disclosed any amino acid sequences of any polypeptide comprising at least 30 or at least 50 contiguous amino acid residues of SEQ ID NO:1, or (ii) a polypeptide comprising the amino acid sequence of residues 1 through 75 or 76 through 149 SEQ ID NO:1 or amino-acid sequences of claimed antibody, that can specifically bind to said polypeptide and can be used for purification and detection striamin protein of SEQ ID NO:1 or for antibody therapy.

Applicant has disclosed a limited number of species; therefore, the skilled artisan cannot envision all the contemplated amino acid sequence possibilities recited in the instant claims. Consequently, conception in either case cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. The sequences themselves are required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).

A description of a protein by functional language in the absence of a structure is not considered sufficient to show possession of the claimed invention. A description of what a material does rather than of what it is, usually does not suffice. See Fiers, 984 F.2d at 1169-71, 25 USPQ2D at 1605-06. It is only a definition of a useful result rather than a definition of what achieves that result. Many species may achieve that result. The definition requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 /f.2d 1516, 1521, 22 USPQ 369, 372-73 (Fed. Cir. 1984) affirming the rejection because the specification does "little more than outline[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what the material consists of (e.g. structural feature), is not a description of that material.

The Examiner notes that the claimed invention which is drawn to a genus of antibody sequences may be adequately described if there is a (1) sufficient description of a representative number of species, or (2) by disclosure of relevant, identifying characteristics sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. To satisfy the disclosure of a "representative number of species" will depend on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. "Relevant, identifying characteristics" include structure or other physical and /or chemical properties, functional characteristics coupled with a known or disclosed correlation between function and structure, or a combination of such identifying characteristics sufficient to show the applicant was in possession of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

14. Claims 34-41 and 51 would be allowable if rewritten or amended to overcome the objection set forth in this Office action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 571/273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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